Sustainability Assessment of product life cycles – Results overview

08.11.2013

Janssen Pharmaceutica NV
PDMS – Technical Operations - EHS²

In collaboration with the **Ghent University**
Department of Sustainable Organic Chemistry and Technology


Agenda

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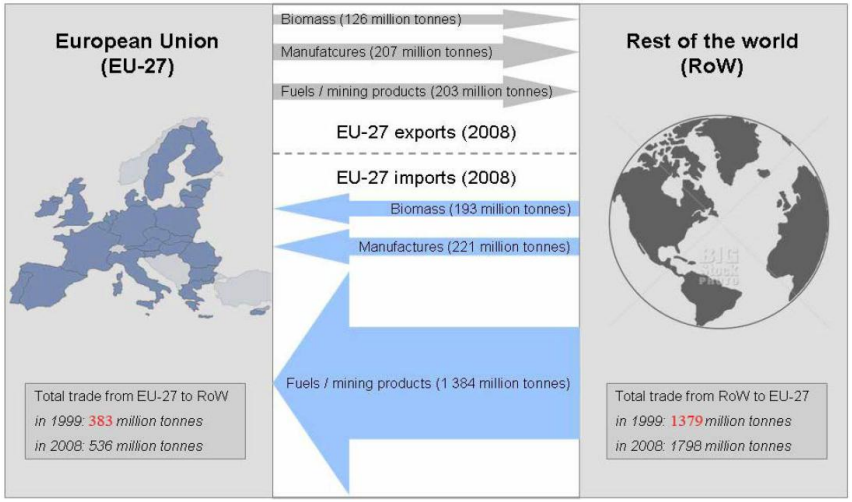
- Introduction – Life Cycle Assessment (LCA)
- Past, current and future LCAs
- General results and discussion

Introduction – Life Cycle Assessment (LCA)

Introduction: Our external environment



Legislation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Contents

II Non-legislative acts

RECOMMENDATIONS

2013/179/EU:

★ Commission Recommendation of 9 April 2013 on the use of common methods to measure and communicate the life cycle environmental performance of products and organisations (1) 1

R&D Programs

Innovative Medicines Initiative

i-CLEANTECH VLAANDEREN enabling the future

CHEM21

FISCH

J&J Janssen

EARTHWARDS™ strives to improve the environmental performance of a product by:

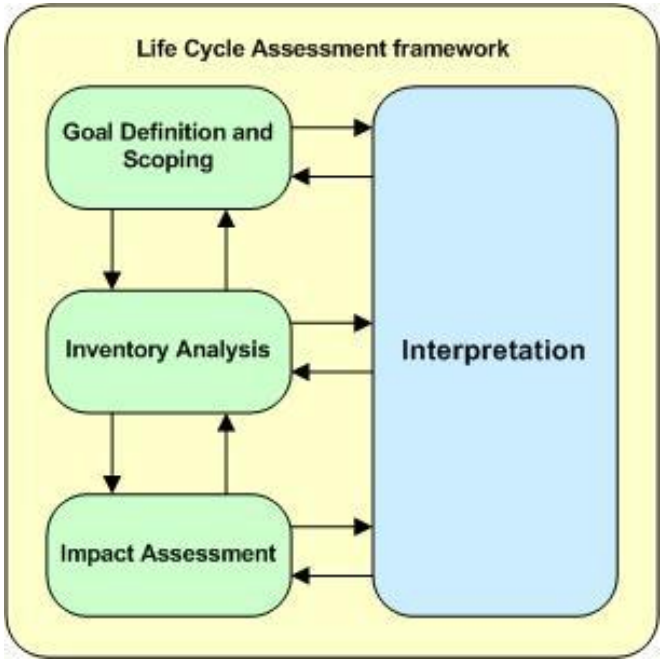
- Reducing materials, energy, water and waste
- Utilizing safer chemicals
- Developing more efficient packaging
- Driving innovation

Introduction: Life Cycle Assessment (LCA)

- Assessment of the **potential environmental impact** of a given **product or service within the production chain** and throughout its **lifespan**

1. Goal and scope definition
2. Life Cycle Inventory (LCI)
3. Life Cycle Impact Assessment (LCIA)
4. Interpretation

Areas of Protection (AoP):
1. Natural Resources
2. Human Health
3. Ecosystem quality

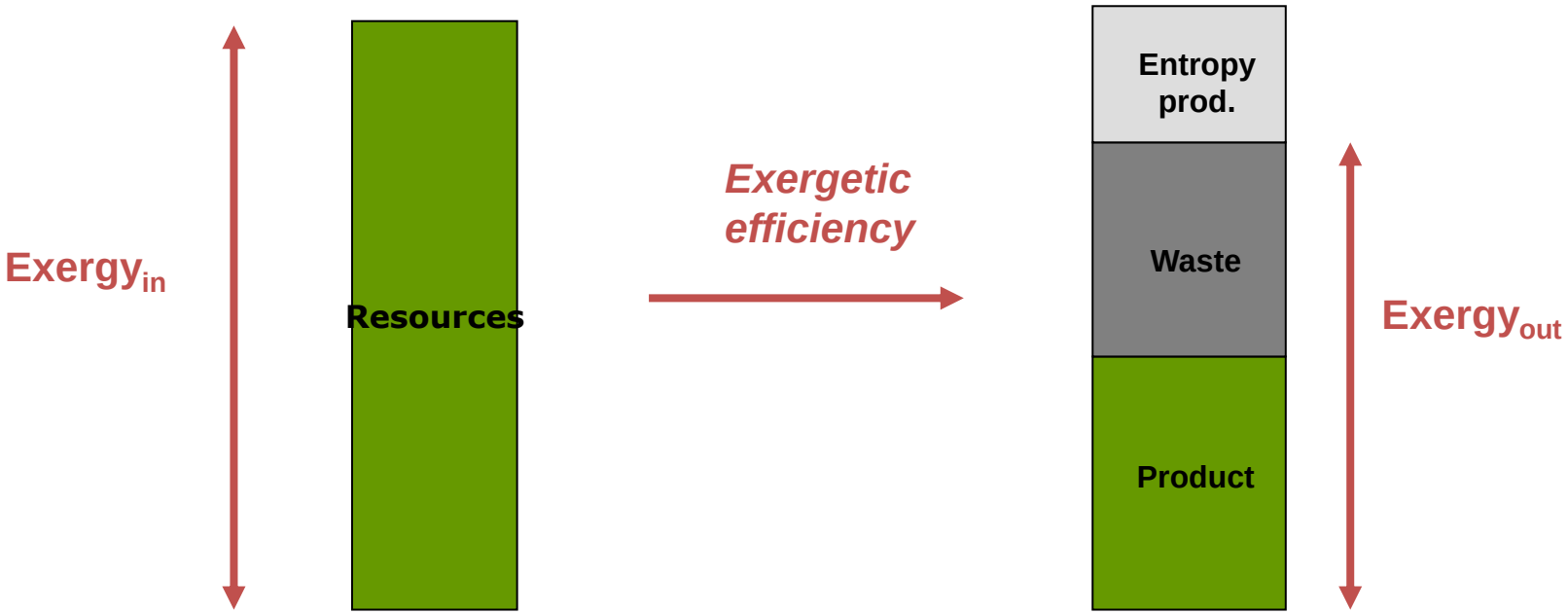


Driver of industrial production/consumption: Resources

- Correlation between resource use and other environmental impacts
- Need for a more holistic view on technology and environment:
  - not only end-of-pipe
  - complete supply chain
  - preventive rather than clean-up
  - act pro-actively through resource management
  - direct link with economic potential

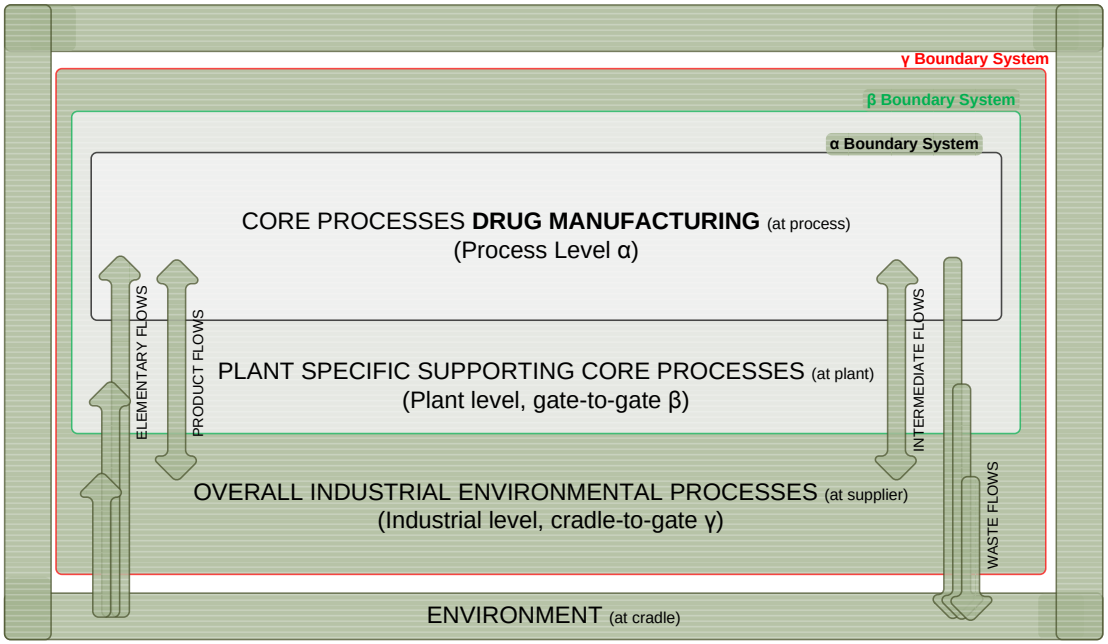
What with the resources?
Exergy Analysis

- How to quantify all different kinds of resource? Energetic, physical resources?



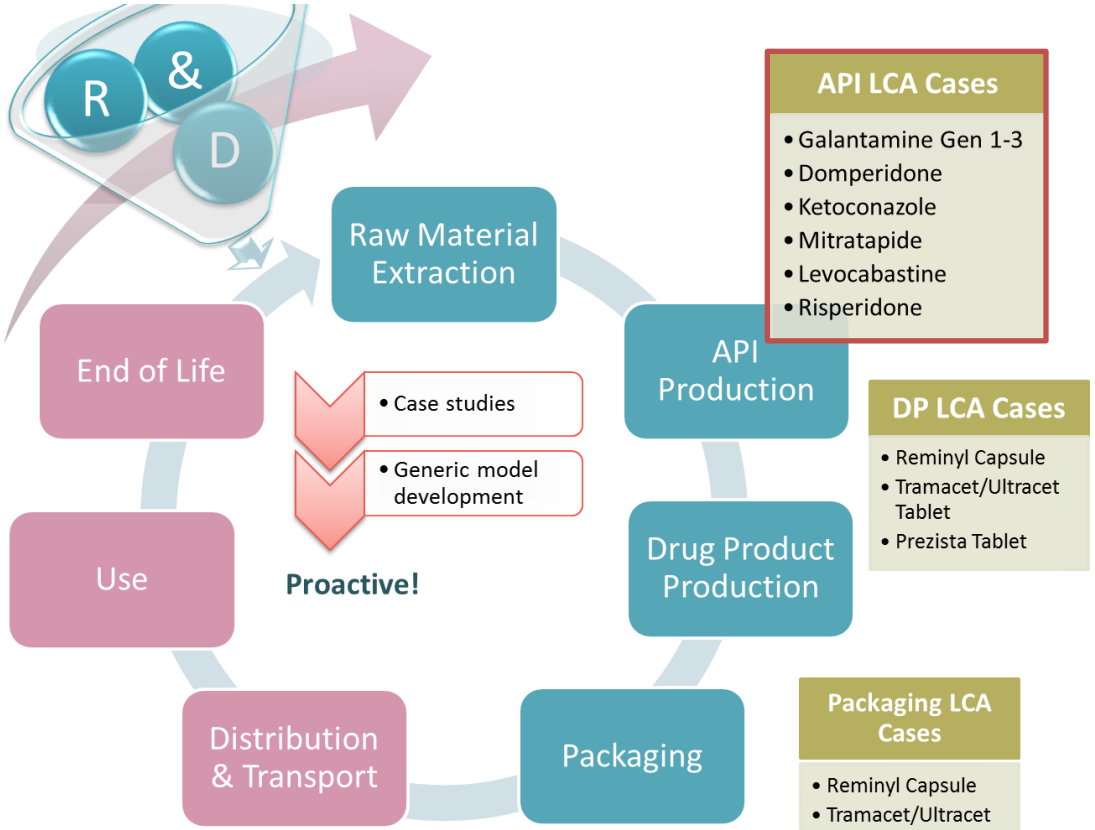
Life Cycle Assessment – What with the resources? Exergetic LCA

- Combination of Process Analysis (EA) and Exergetic Life Cycle Analysis (ELCA)
  - Identification, localization and reduction of environmental burdens




Past, current and future Projects

Past, current and future Projects

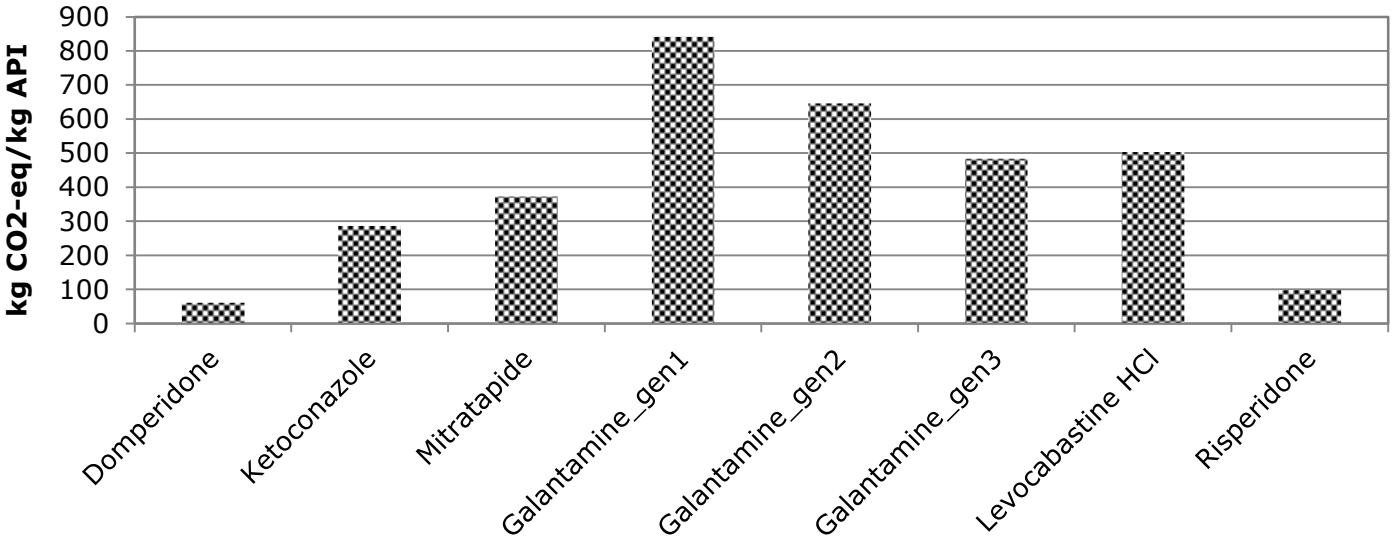


API ELCA Cases

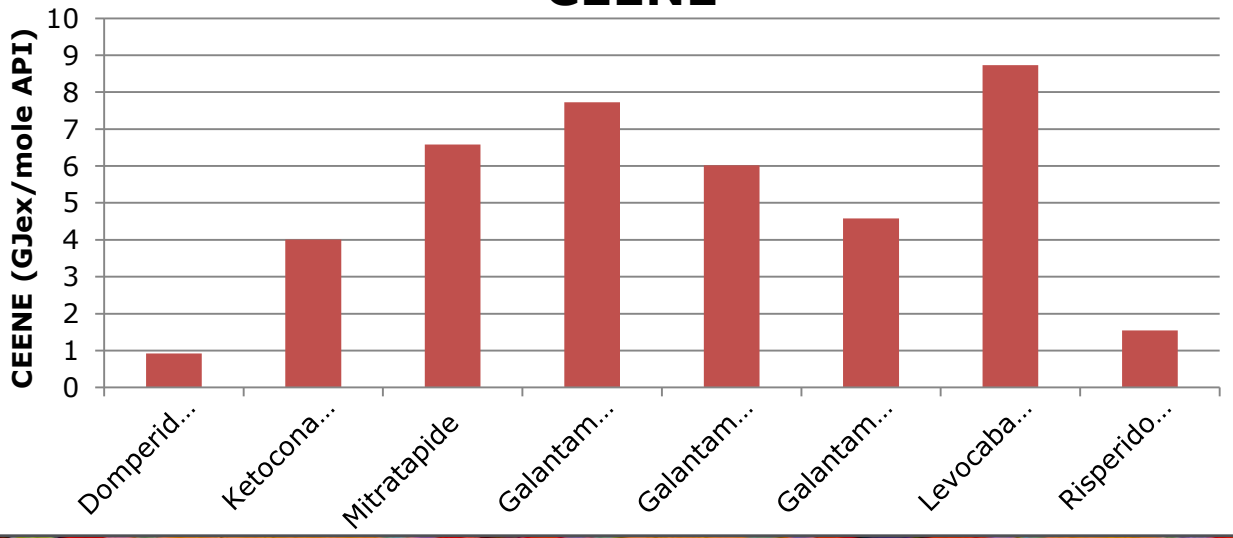
- Assess environmental sustainability ("greenness") and resource consumption of API synthesis steps of:
  - Domperidone (10 steps)
  - Ketoconazole (8 steps)
  - Levocabastine (8 steps)
  - Mitratapide (7 steps)
  - Risperidone (7 steps)

- 1-9 GJ_{ex}/mole API → eq. 250-2250 km transport family car
- 65% of resource extraction of API production due to fossil resources at the cradle
- 45% of resource losses occur at JNJ plant Geel (BE), 55% through supply chain

IPCC GWP 100a

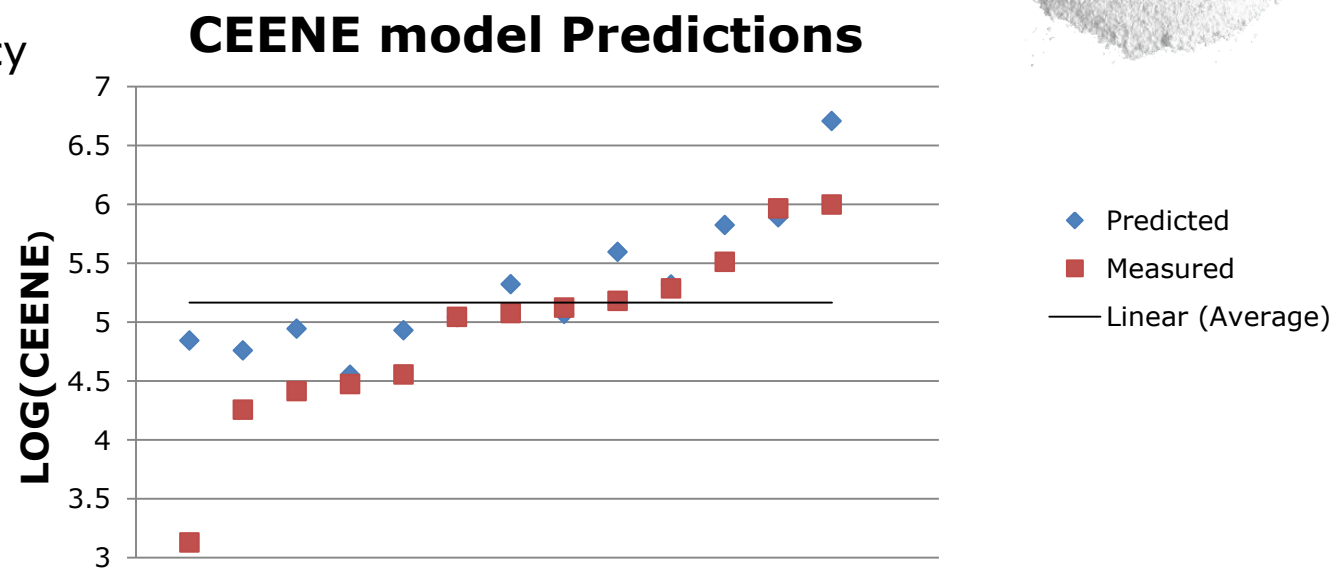


CEENE



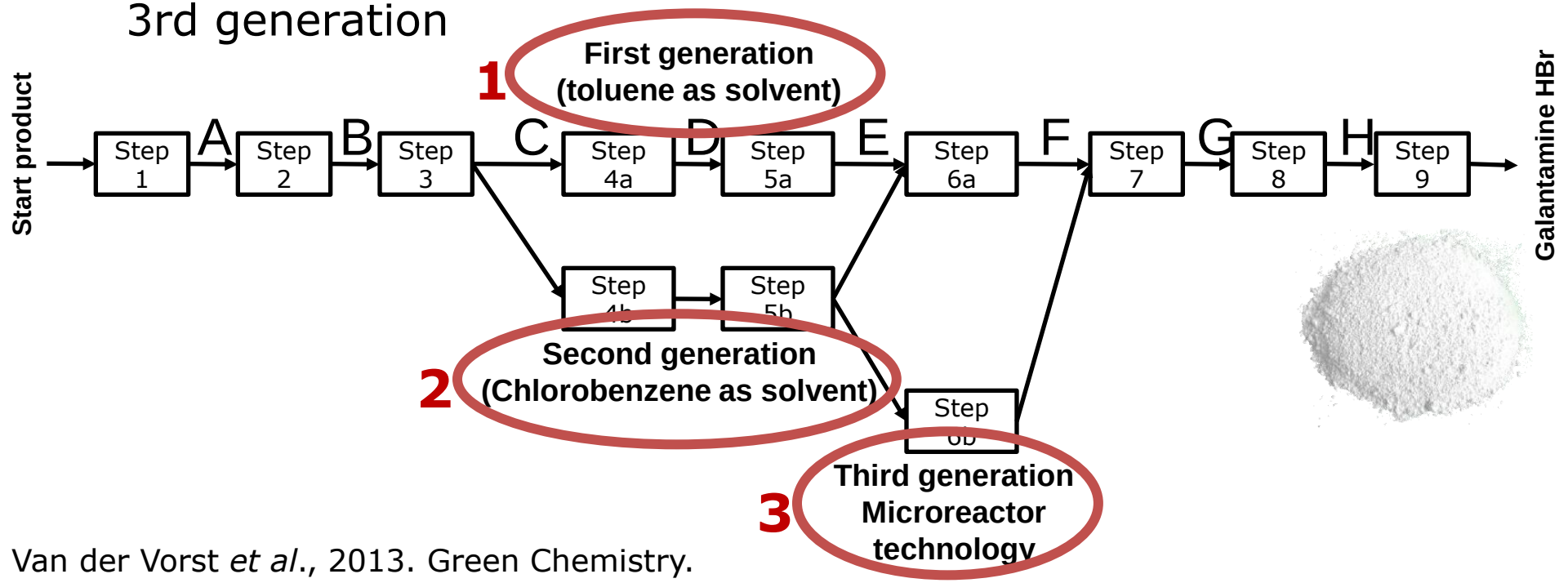
API ELCA Cases

- New (preliminary): correlation models to predict resource extraction due to API synthesis steps based on 3 process dependend parameters:
  - Organic Solvent Use
  - # Reactors
  - Molar efficiency



API ELCA Cases: Galantamine generations

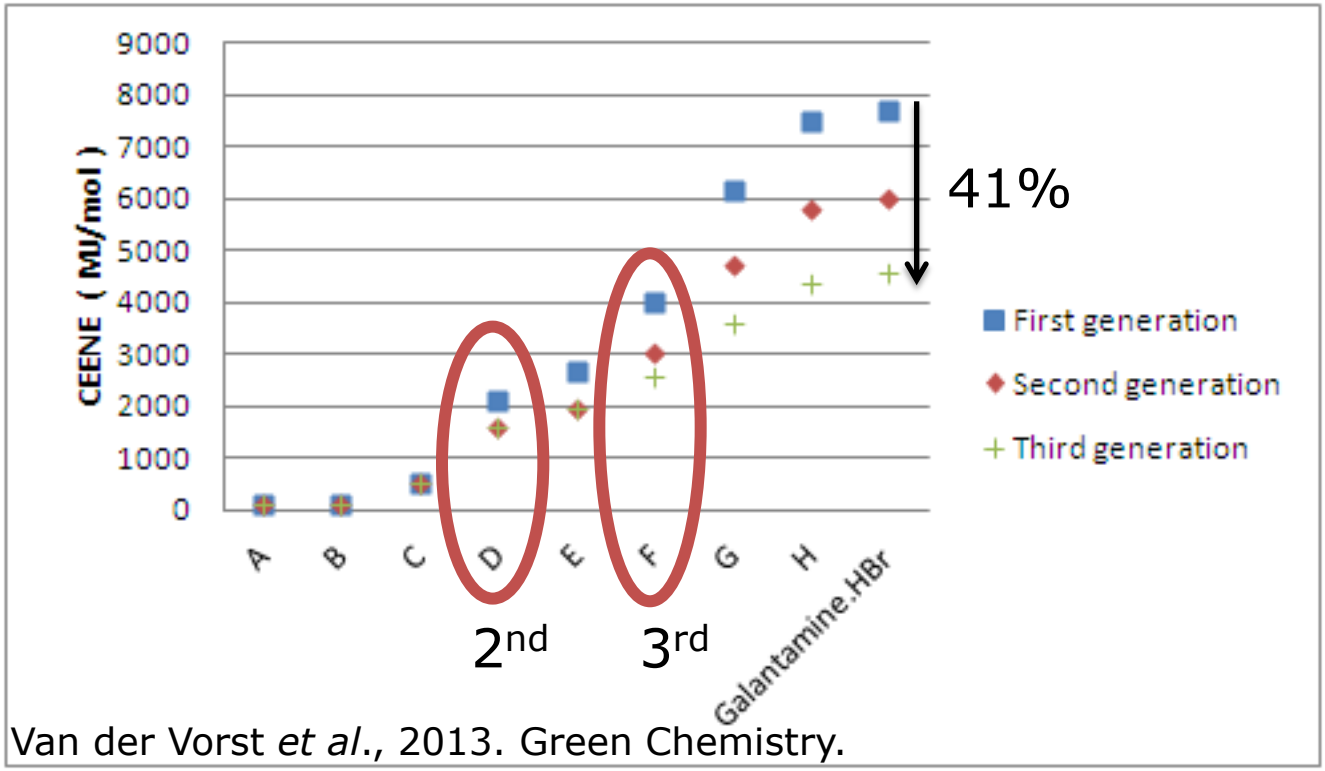
- Comparative environmental sustainability assessment of 3 generations of Galantamine
- +- 41% reduction in integral resource consumption 1st → 3rd generation



Van der Vorst *et al*., 2013. Green Chemistry.

API ELCA Cases: Galantamine generations

- Resource consumption reduction of Galantamine synthesis steps (MJ_{ex}/mole intermediate)



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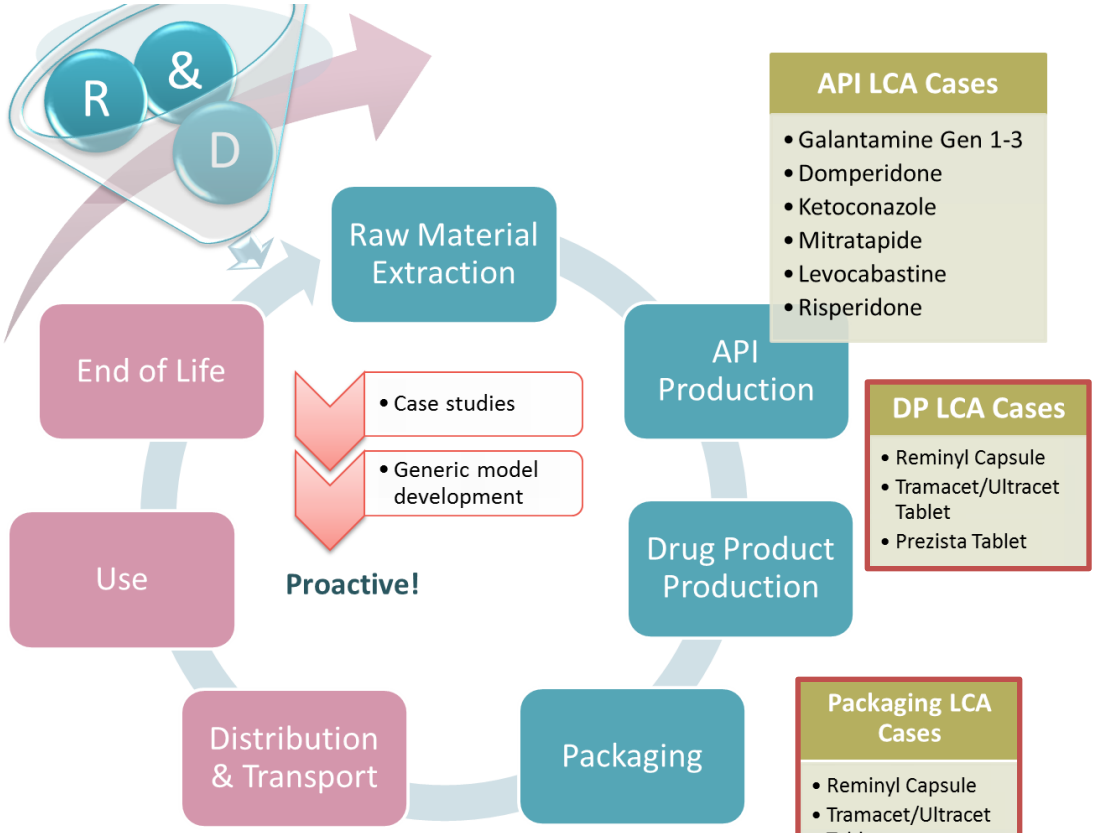
Past, current and future Projects



DP ELCA Cases

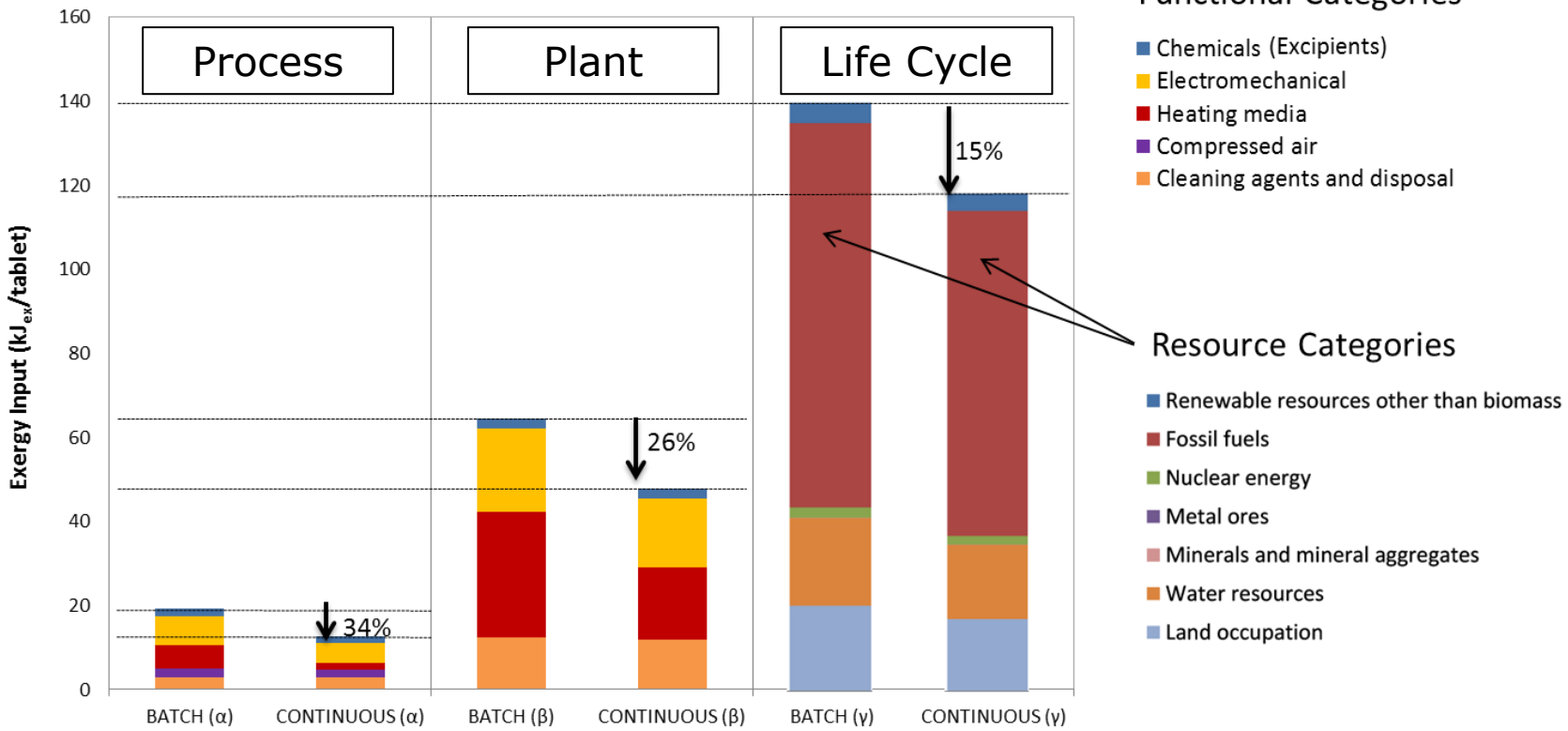
- Full life cycle evaluation of Galantamine.HBr (Reminyl®, prolonged release capsules)
- Batch versus continuous Drug Product (DP) Production? The case of Tramacet®
- Upscaling of R&D to manufacturing batch sizes in DP Production: impact on the resource footprint

Tramacet

Exergetic sustainability assessment of **batch versus continuous** wet granulation based pharmaceutical **tablet manufacturing**: a cohesive analysis at three different levels

De Soete *et al*., 2013. Green Chemistry.

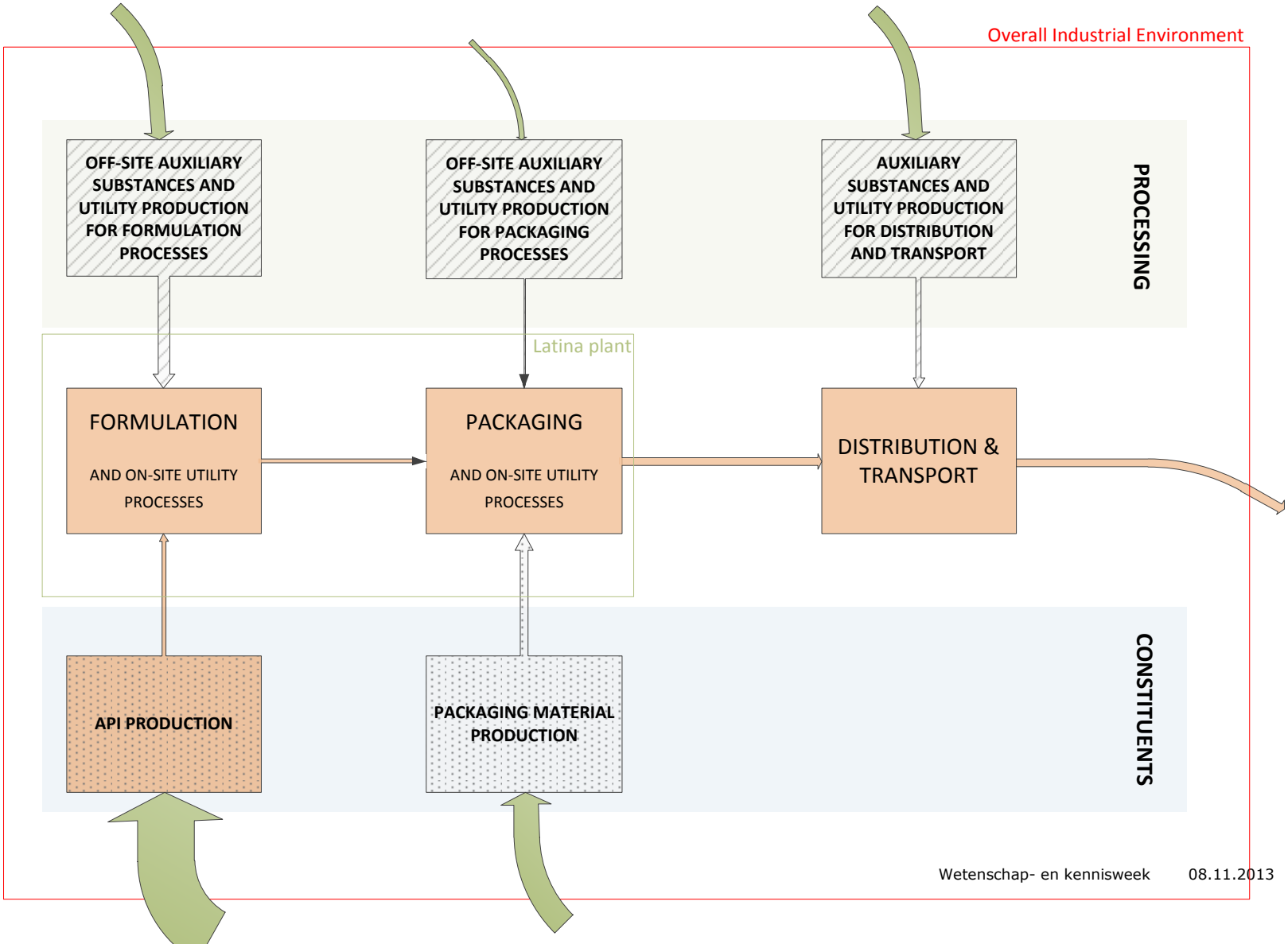
Tramacet DP Production



- **Tablet CEENE: 65% fossil, 15% water resources, 15% land occupation/biomass, 5% renewables resources other than biomass**

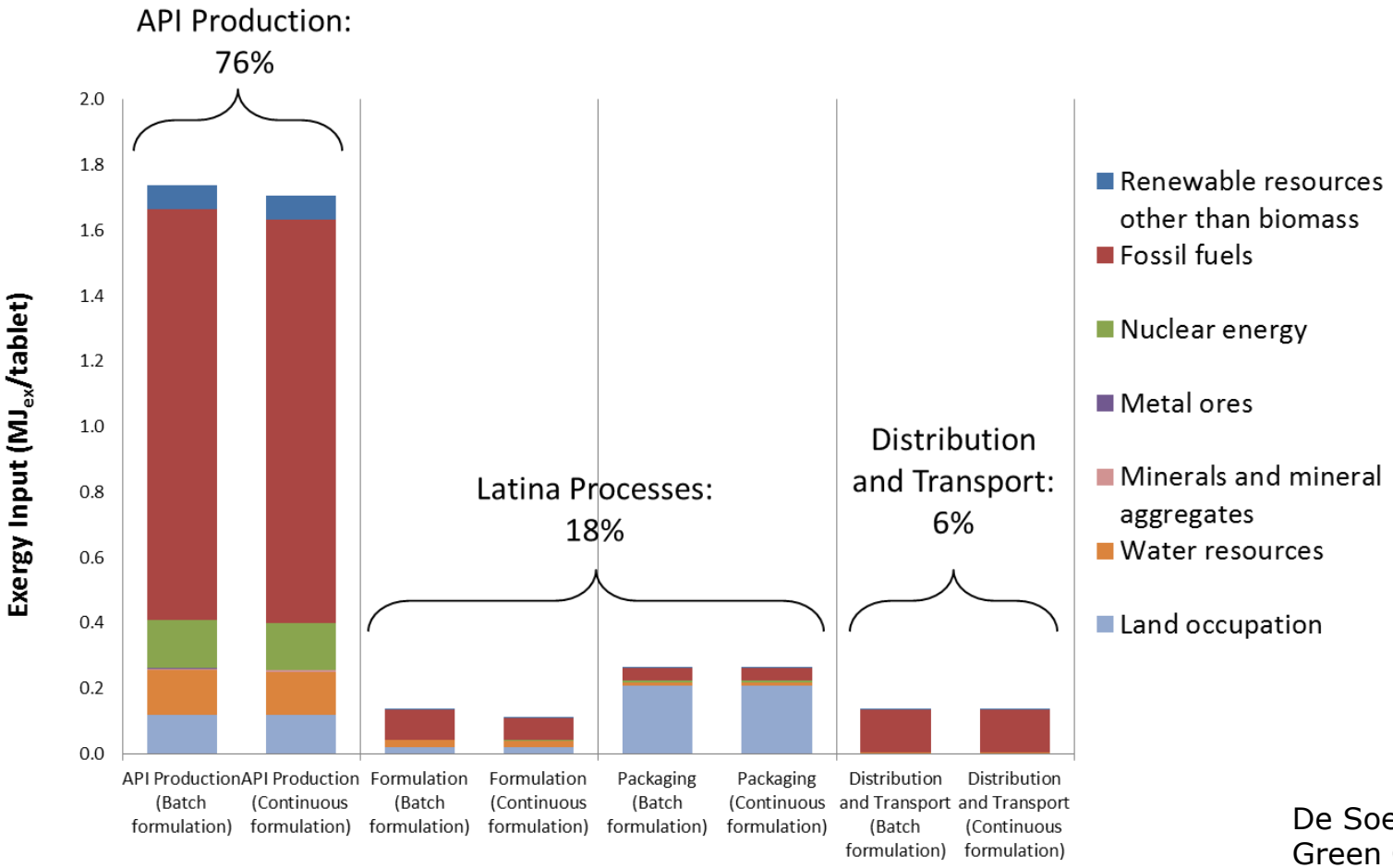
De Soete *et al.*, 2013. Green Chemistry.

Tramacet: what about the supply chain?



Tramacet: what about the supply chain?

- Prevailing for **high dose drugs** (TRAMACET® 82%$_w$ API)



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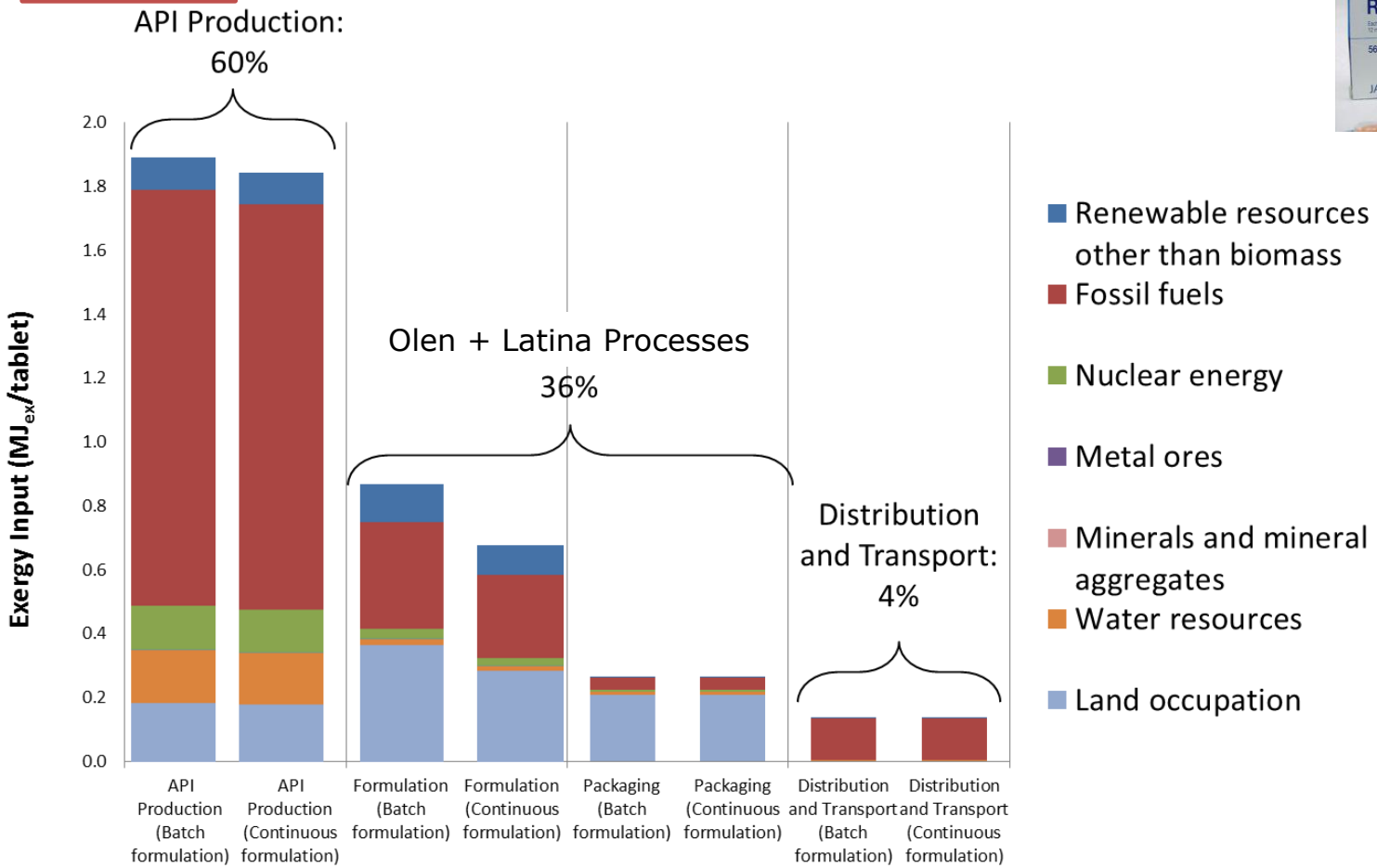
Reminyl: what about the supply chain?

- **Low dose drug** estimation (REMINYL® ±40%$_w$ API) → formulation importance!



Tramacet Results

- ConsiGma™ huge step forward towards Greener Formulation Processes
- Further reduce impact through:
  - In-line blending and in-line coating
  - Re-using treated wastewater for cooling or cleaning purposes
  - Recycling exhaust air for heating purposes
- Sensitive parameters:
  - API dosage
  - # tablets per folding box (packaging)

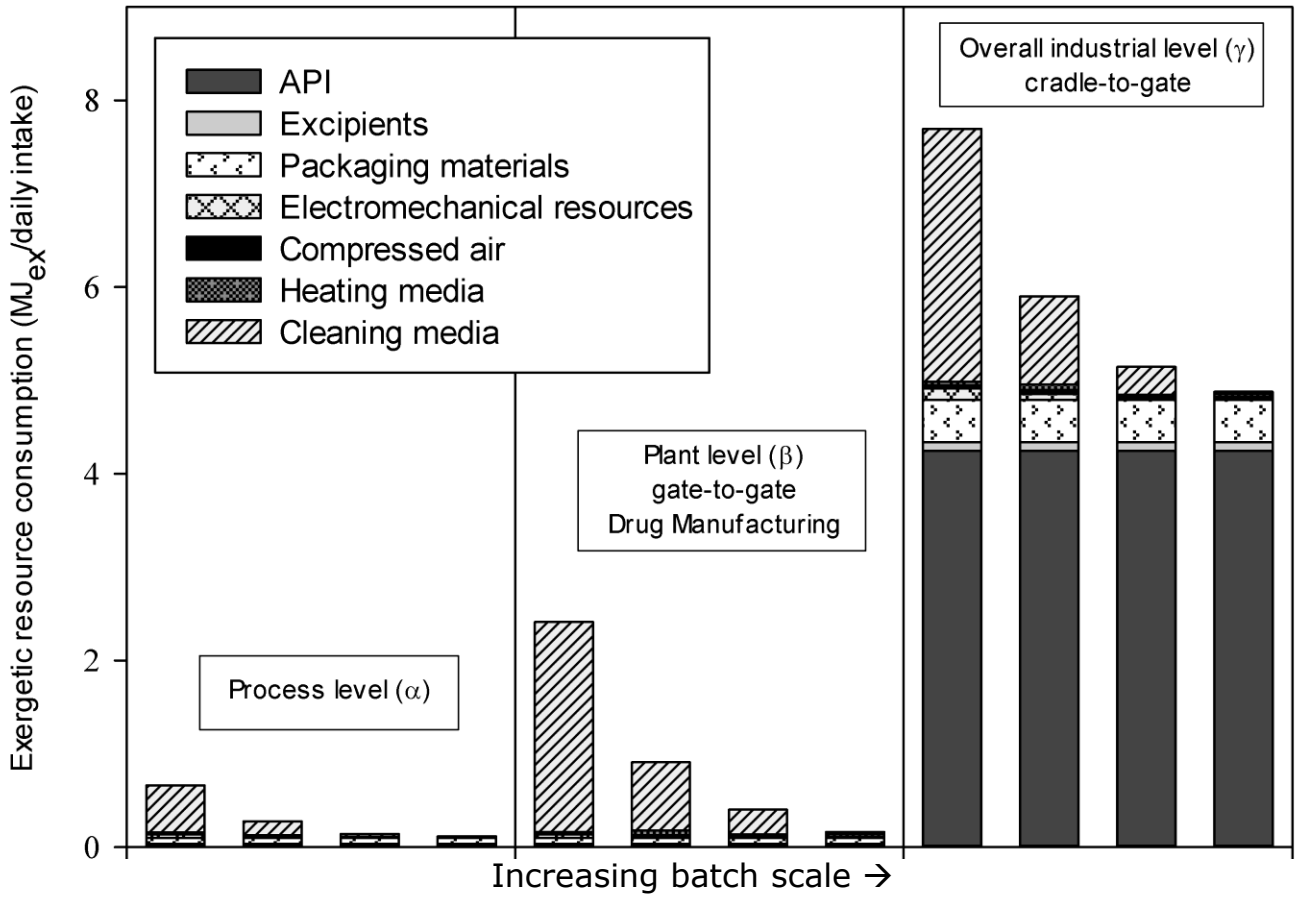
De Soete *et al*., 2013. Green Chemistry.

Prezista

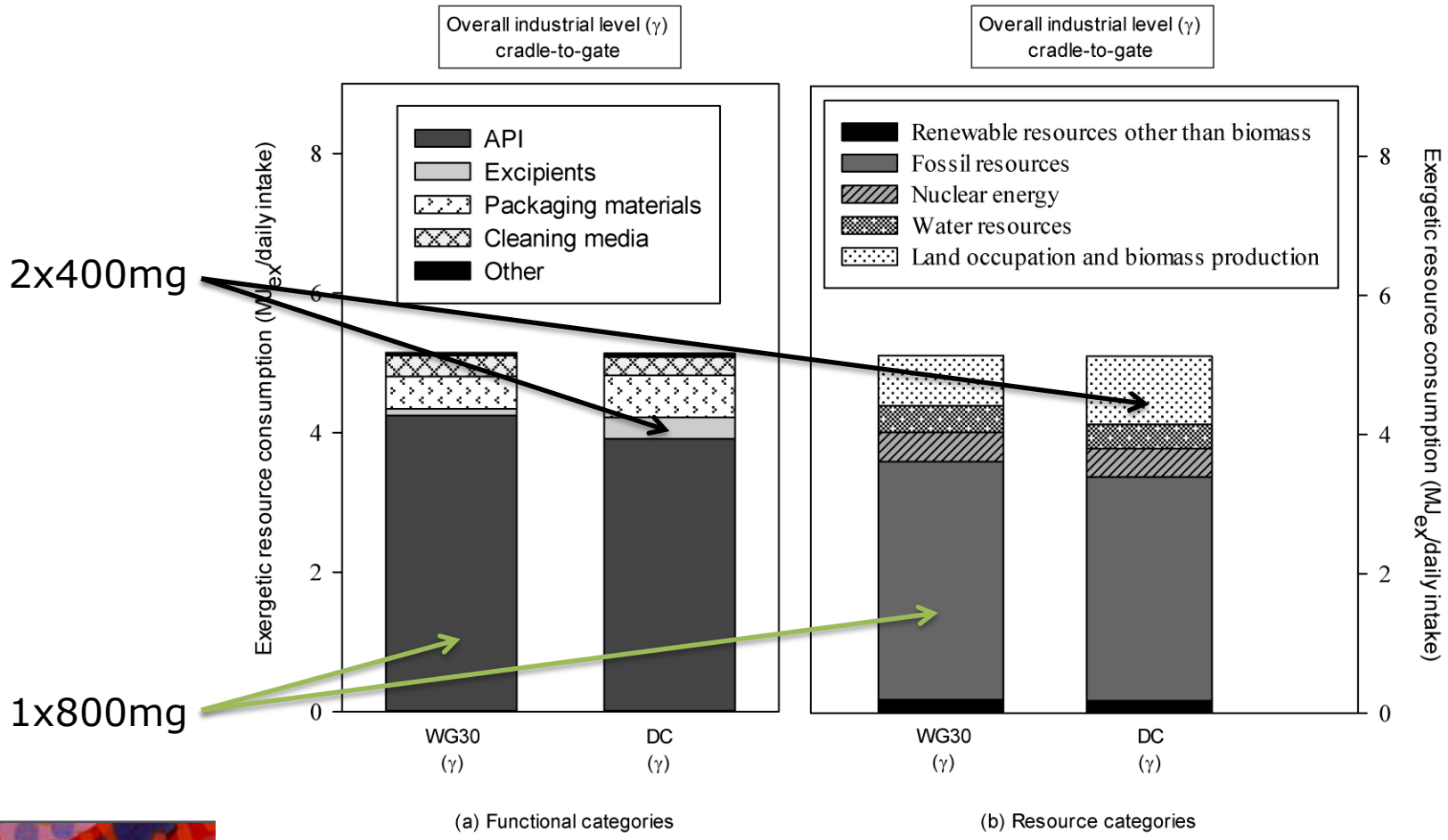
- Environmental Resource Footprinting of Drug Manufacturing:
  1. Effects of Scale up (WG1 → WG5 → WG30 → WG240)
  2. Effects of Tablet Dosage (2x400mg tablet vs 1x800mg tablet)

De Soete *et al*. Resources, Conservation and Recycling.

Prezista: effects of scale-up



Prezista: effects of tablet dosage



Prezista Results

- More efficient at higher scale, mainly due to use of better performing cleaning procedures (e.g. CIP) and use of resource efficient equipment
- In meeting social and economic demands by launching the PREZISTA® 800 mg tablet, no trade-off in environmental burden occurred
  - Resources for extra granulation step cancelled out by more efficient packaging phase

De Soete *et al*. Resources, Conservation and Recycling.

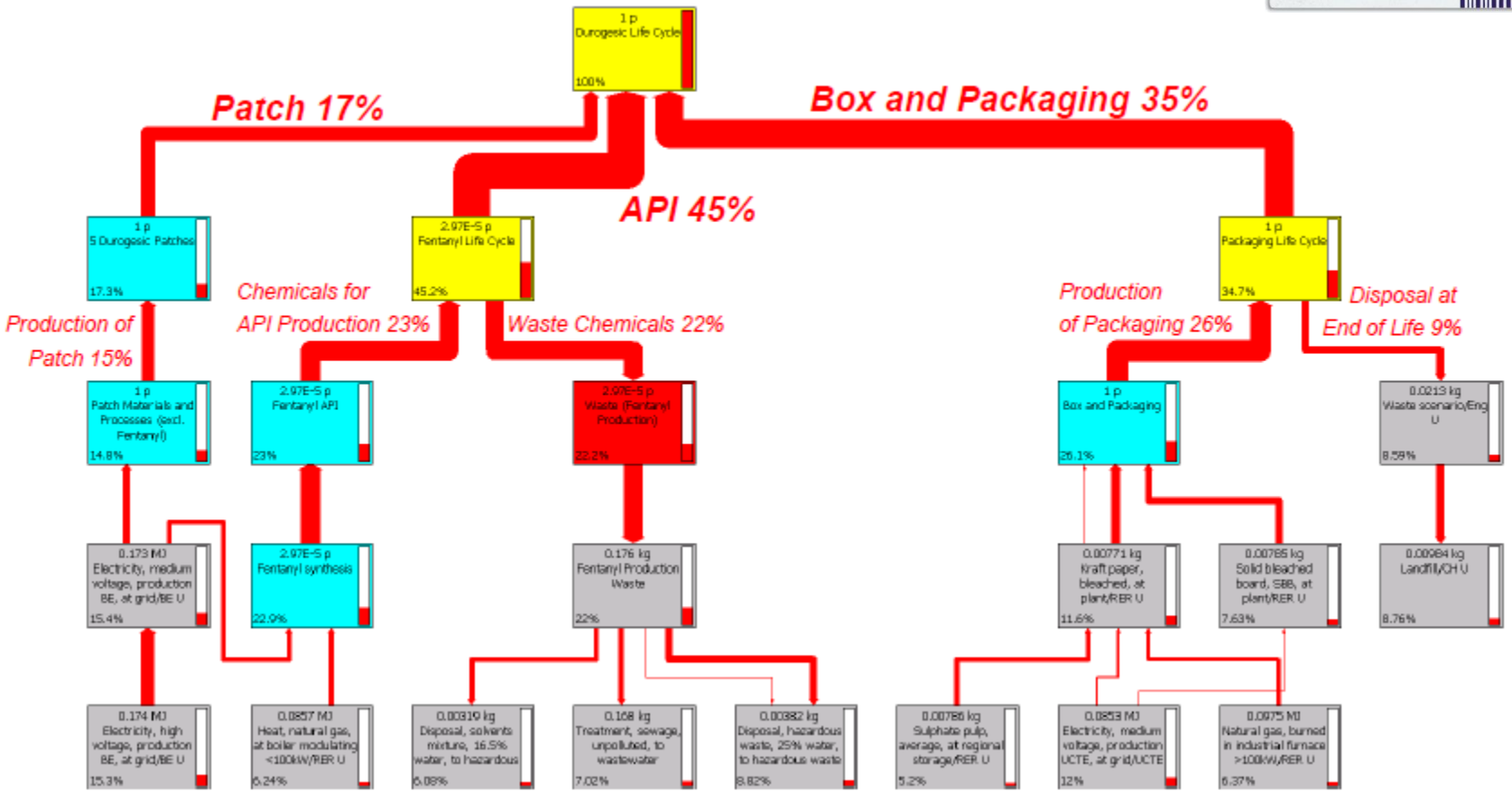
Carbon Footprinting

- Carbon Footprinting of Durogesic®
  - Deloitte
  - Patch + primary and secondary packaging: +- 50% of total footprint
- Risperdal Consta® and Xeplion® Carbon Footprint
  - BestFootForward (BFF)

	Consta			Xeplion		
	Per patient year	Per dose		Per patient year	Per dose	
	kgCO2e	kgCO2e	%	kgCO2e	kgCO2e	%
Raw Materials	0.21	0.0083	0.3	3.75	0.2881	5.5
Packaging	6.06	0.2332	8.7	2.67	0.2050	3.9
Energy	3.30	0.1328	4.7	35.58	2.7366	52.2
Manufacturing Waste	1.89	0.0729	2.7	-0.25	-0.0195	-0.4
Distribution between plants	4.33	0.1666	6.2	0.11	0.0084	0.2
Retail	52.84	2.0322	75.6	25.86	1.9896	38.0
EoL	1.10	0.0424	1.6	0.38	0.0293	0.6
Total	69.9	2.688	100	68.1	5.238	100

Carbon Footprinting: Durogesic

(PE International)



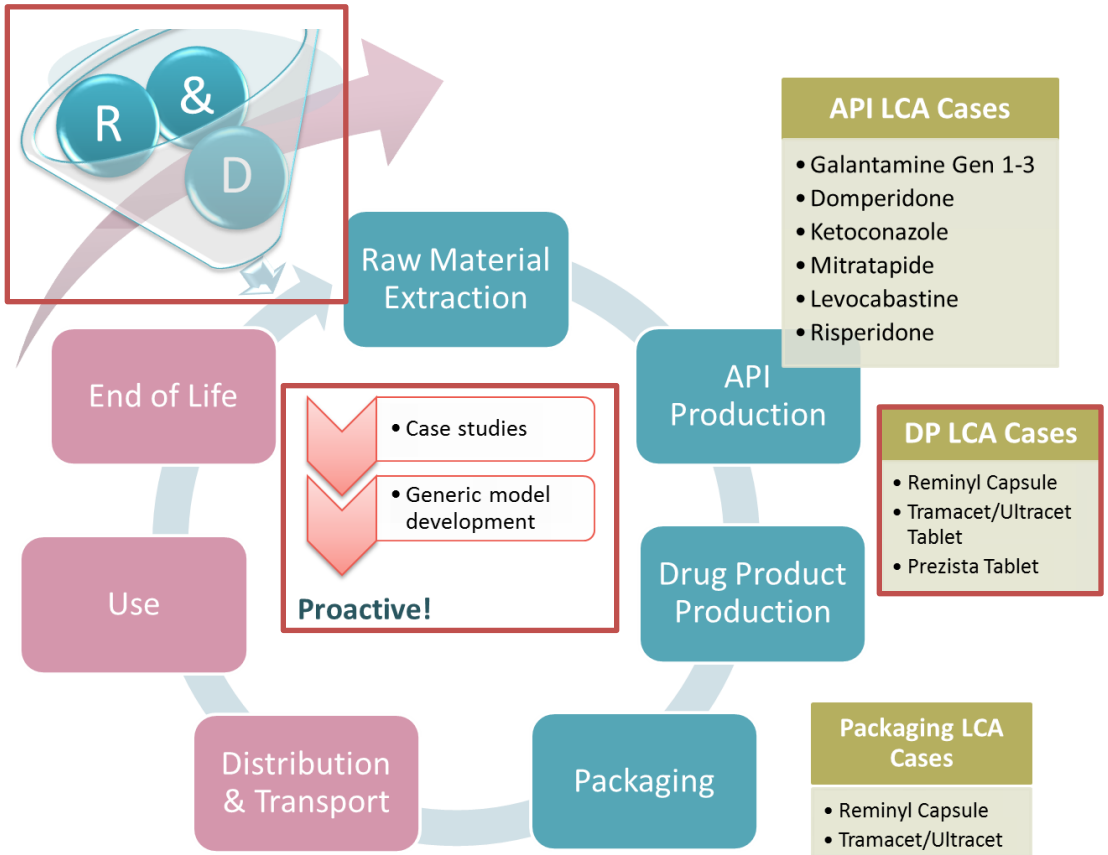
Current and future projects

- Environmental sustainability assessment of Janssen Pharmaceutica catering and hospitality services

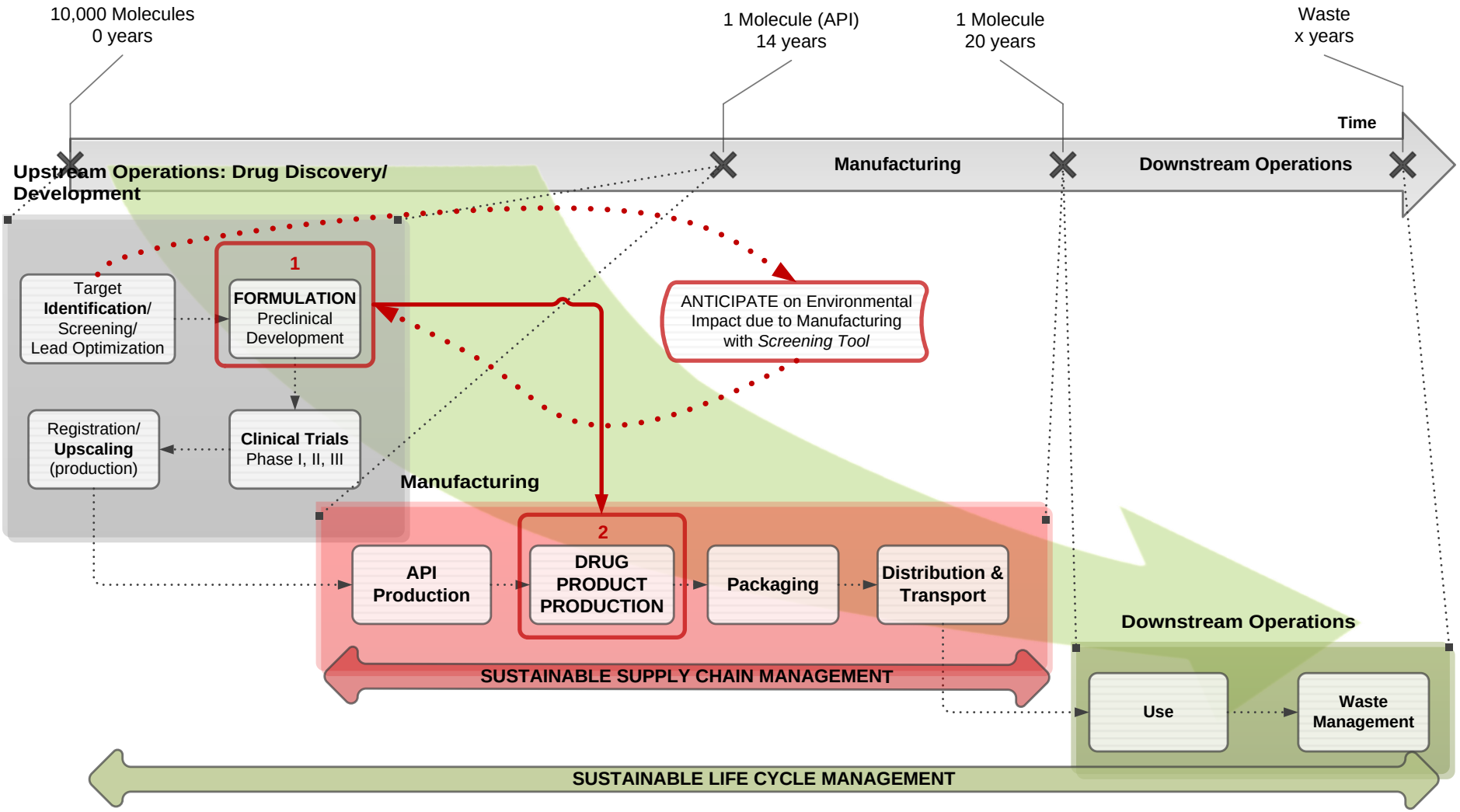
- Resource footprinting of biological technological production of Stelara®

- Balancing positive and negative human toxicity effects of pharmaceutical production processes

Past, current and future Projects



Development of a Generic Screening Tool to be used in Environmental Sustainability Assessment of Pharmaceutical Formulations



General Results and Discussion

Results overview and future outlook

- Substantial knowledge on environmental impact of API synthesis processes
- Dosage Forms: case specific; Product Category level too aggregated
- Need to move downstream in supply chain: what about distribution networks? Logistics? Use phase? Waste management?
- Take into account other impacts as well ('Human Health', PEF impact categories)
- LCA → Sustainability assessment. What about social/economic impacts?


Q&A

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